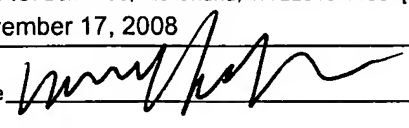
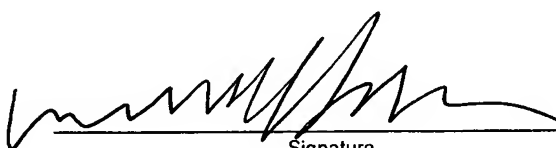
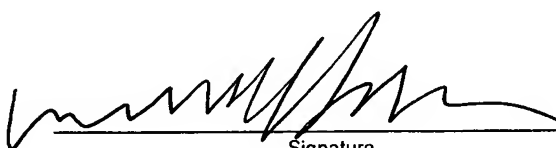
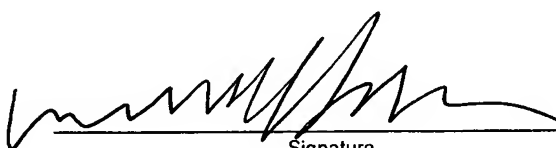




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PTO/SB/33 (10-08)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 12,616						
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on <u>November 17, 2008</u></p> <p>Signature <u></u></p> <p>Typed or printed <u>William W. Haeliger</u> name _____</p>		Application Number 10/826,901	Filed April 19, 2004					
		First Named Inventor Hovanes John Ter-Zakarian						
		Art Unit 1617	Examiner Sreeni Padmanabhan					
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table><tr><td><input type="checkbox"/> applicant/inventor.</td><td rowspan="4"> _____ Signature <u>William W. Haeliger</u> _____ Typed or printed name <u>323 684-2707</u> _____ Telephone number <u>November 17, 2008</u> _____ Date</td></tr><tr><td><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td></tr><tr><td><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>17,120</u></td></tr><tr><td><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>				<input type="checkbox"/> applicant/inventor.	 _____ Signature <u>William W. Haeliger</u> _____ Typed or printed name <u>323 684-2707</u> _____ Telephone number <u>November 17, 2008</u> _____ Date	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>17,120</u>	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____
<input type="checkbox"/> applicant/inventor.	 _____ Signature <u>William W. Haeliger</u> _____ Typed or printed name <u>323 684-2707</u> _____ Telephone number <u>November 17, 2008</u> _____ Date							
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)								
<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>17,120</u>								
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____								

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



REASON

Examiner has stated on page 5 of the final rejection as follows:

"In this case, there is reasonable suggestion by the prior art references that a skilled artisan would have expected a leukotrene receptor antagonist would have been useful in treating patients with familial Mediterranean fever".

This amounts to a "could have" type "expectancy" that a leukotrene receptor antagonist would have been useful in treating patients with familial Mediterranean fever. That is not enough reasons to provide a teaching or incentive supporting the combination. Caralla, 804 F.2d at 140, 231 USPQ at 647 (citing ACS Hosp. Syss., Inc., 732 F.2d at 1577, 221 USPQ at 933).

In the present case, the desirability, or expectancy of usefulness, (see Action page 6, last paragraph, line 9) of making the total and specific combinations of each of

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claims 1, 3, 4 and 5 is not suggested by any reference or combination of the references, for reasons stated in paragraphs 1-9 below. Examiner equates "would have expected a leukotreneine receptor antagonist would have been useful" with "might offer", on page 5, last 8 lines of the Action. In this regard, the U.S. Court of Appeals for the Federal Circuit has stated that, "the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. None of the four references suggests their desirable combination to meet the specifics of applicant's claims.

Note also the mere fact that the prior art could be modified does not make such a modification obvious unless the prior art suggests the desirability of doing so. In re Gordon, 732 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir., 1984).

As previously urged, reconsideration and withdrawal of the claim rejections are respectfully solicited, in view of the following:

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1) the arguments set forth in the prior amendment, deemed persuasive in the Action dated 3-19-08, (citing Frenkel) to the extent they are also applicable to the combination of Frenkel in view of Sawyer, Sims and PDR. (Sawyer substantially repeating the Frenkel leukotriene teachings);

1a) Examiner's concessions as to what the references do not specifically teach, listed in detail on page 3 of the Final Rejection;

2) Failure of Sawyer or other cited art to teach or suggest the specific daily, orally administered, limited dosage between 5 and 15 milligram of LTRA;

3) Failure of Sawyer or other cited art to teach or suggest the continuance of such dosage, as per 2) above, at said average daily basis level, and as long as the FMF symptoms continue;

4) The Sawyer dosages "from about 5 to about 500 mg, and/or from about 0.5 to about 300 mg/kg per day (column 116), are not specifically targeted to FMF treatment, (Sawyer lists over 65 diseases for treatment) or to patients suffering only from FMF, as applicant herein

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claims, and the recited Sawyer dosage levels are so wide as to encompass all 65 of his listed diseases so as to be non-suggestive of the narrow 5-15 mg level of claim 1 herein, or the specific 10 mg level claimed herein for treating FMF.

5) Applicant's narrow mg daily dosage level, targeted to FMF, as referred to, and as claimed, as it relates to the claimed continuance of administration for so long as FMF symptoms continue, is not suggested by Sawyer or other art.

6) Applicant's narrow mg daily dosage level, as referred to, and as claimed in claims 3 and 4, as it relates to such claimed continuance of administration for periods of time varying from 5 months to 2 ½ years for treating only FMF, is not suggested by Sawyer or other art.

7) Failure of Sawyer or other art to teach or suggest specific use of ZAFIRUCAST or SINGULAIR tablets in the totalities of claims 3 and 4.

8) Applicant's actual treatment of patients, with FMF, as per the TEST results in the application.


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9) All of the reasons set forth in 1) and 8) above.

A telephone discussion of possible Examiner proposed further re-wording of any of the claims 1 and 3-5 in the interests of arriving at acceptable wording, is respectfully invited.

Allowance is respectfully solicited.

Respectfully submitted,



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323 684-2707

WWH:hk

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